



Vermont Vaccines for Children & Vaccines for Adults Restitution Policy

Introduction: Accountability for vaccine is an essential requirement of the Vermont Department of Health's Vaccines for Children (VFC) and Vaccines for Adults (VFA) programs. Vaccines are costly and federal and state funds for vaccine purchases are limited. Vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until administration.

Definitions:

Waste: Any non-viable vaccine that cannot be used. This includes expired, spoiled and lost vaccine.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that is stored or transported outside of the limits of the approved cold chain procedures or any vaccine that has been pre-drawn and not used within acceptable time frames. Always consult with the VDH Immunization Program before determining that the vaccine is spoiled.

Lost: Any vaccine ordered but not delivered or not delivered in a timely manner by the commercial carrier or delivery service that results in lost and/or spoiled vaccine.

Policy: As part of the enrollment process for both the VFC and VFA programs, providers agree to comply with VFC & VFA requirements for ordering, storage, handling and accountability of vaccine. Beginning July 1, 2011, enrollment in either the VFC or VFA vaccine program(s) will include an agreement that failure to store or handle vaccines properly may result in the practice being liable for mishandled/wasted doses. The practice will assume responsibility to replace vaccine on a dose for dose basis. There is a wide range of potential vaccine storage and handling issues that may result in wasted vaccine. The Immunization Program will review each incident where more than 10 doses of vaccine were wasted, to determine whether restitution will be required. If restitution is required the practice will not receive additional VFC or VFA vaccine until they have shown that replacement vaccine has been ordered and the problem that caused the wastage has been corrected.

Situations Requiring Restitution: The following situations are examples of negligence that would lead to non-viable vaccine which may require restitution. This list is not exhaustive.

- Failure to rotate vaccine stock or notify the Immunization Program 60 days or more prior to vaccine expiration date
- Repeated waste of vaccine due to drawing up of vaccine prior to patient screening
- Vaccine left out of the refrigerator or freezer that becomes non-viable
- Freezing vaccine that is meant to be refrigerated
- Refrigerating vaccine that is meant to be frozen
- Refrigerator or freezer door left open or ajar by provider staff
- Vaccine that is considered spoiled due to provider staff not checking, reviewing or appropriately interpreting refrigerator and/or freezer temperatures twice daily
- Refrigerator unplugged or electrical breaker switched off for extended periods of time
- Failure to contact the Immunization Program when refrigerator or freezer malfunction results in temperature fluctuations
- Refrigerator or freezer malfunctions or power outages in which provider staff fails to follow their Vaccine Management Plan and fails to contact the Immunization Program
- Planned power outages in which provider staff fails to take precautions to maintain appropriate storage of vaccine
- Transportation of vaccine inappropriately: unnecessary transportation of vaccine without Immunization Program consent and/or failure to appropriately maintain cold chain during transportation
- Replacement vaccine: situations in which health care providers must re-vaccinate due to previous administration of non-viable vaccine or improper administration.
- Delivery of vaccine during the provider's stated business hours but the office is closed

Situations That Do Not Require Restitution: The following situations are examples of situations in which loss of vaccine would NOT require restitution. In these situations the provider practice is deemed not to be at fault. This list is not exhaustive.

- Vaccine that is damaged, improperly stored during transit, or not delivered in a timely manner.
- Provider staff move vaccine to their back-up location as outlined in their Vaccine Management Plan, in anticipation of power storage or due to refrigerator or freezer malfunction and the back-up location experiences power outage or equipment malfunction.
- Power interruption or failure due to storms or other weather conditions
- Unanticipated refrigerator or freezer failure that occurs overnight, during the weekend or during a period of time when the provider staff is not present.
- Partially used multi-dose vials of vaccine
- A vial of vaccine that is accidentally dropped or broken by provider staff
- Occasional instances of wasted vaccine due to provider staff error or last minute patient refusal
- Expired vaccine that provider staff has notified the Immunization Program about and redistribution has been made
- Extraordinary situations not listed above which are deemed by the Immunization Program to be beyond the provider's control

Procedure for Restitution: Each incident reported will be reviewed on a case-by-case basis by the Immunization Program to determine whether restitution will be required or if extenuating circumstances exist.

- Call the Immunization Program if you suspect vaccine has been exposed to a situation that would deem it wasted.
- Record lot number, number of doses and expiration date for wasted vaccines under Wasted Vaccines column on your Vaccine Accountability and Order form.
- The next time you place a vaccine order a UPS shipping label and Return Authorization Form will be mailed to your practice.
- When you receive the shipping label and Return Authorization Form follow the instructions for returning vaccine to McKesson Specialty Distribution. These instructions are listed on the form.
- If restitution is required the provider will be asked to submit an invoice to the Immunization Program showing they have privately purchased vaccine to replace the wasted vaccine. Providers should contact their insurance carrier to determine if there is coverage for lost vaccine.
- Failure to replace vaccine will result in a delay of future VFC and/or VFA vaccine orders.

Please contact the Immunization Program if you experience staff changes that impact vaccine storage and handling duties in the practice. Vaccine security depends on proper education and training. If you have any questions concerning this policy, please call the Vermont Department of Health's Immunization Program at (802) 863-7638 or toll free at 1-800-640-4374.